REMARKS

Claim 1 has been amended. Claim 22 has been canceled without prejudice. Accordingly, claims 1-21 and 25 are pending. Support for the amendment to claim 1 is found throughout the specification and claims as originally filed. Accordingly, no new matter has been added.

In response to the Office Action mailed on July 22, 2009, Applicants submit the following remarks.

Rejection under 35 U.S.C. § 101

The Examiner rejected claim 22 under 35 U.S.C. § 101, as allegedly reciting a use claim which is not a proper process claim. Applicants have canceled claim 22. Accordingly, Applicants submit that the rejection is moot.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claim 22 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Specifically, the Examiner states that claim 22 is indefinite because it merely recites a use without any steps delimiting how the use is practiced. As noted above, Applicants have canceled claim 22. Accordingly, Applicants submit that the rejection under 35 U.S.C. § 112, second paragraph is moot.

Rejection of Claims 1, 2, 4-8, 10, 11, 14, 17 and 19 under 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 2, 4-8, 10, 11, 14, 17 and 19 under 35 U.S.C. § 102(b) as allegedly anticipated by Hennessy et al. (U.S. 5,840,324, hereinafter "Hennessy"). Specifically, the Examiner asserts that Hennessy describes a method of combating and preventing parasite infestation of ruminant animals wherein the method includes all of the limitations of the rejected claims.

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985).* More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052 (Fed. Cir. 1994).* "To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim." *Brown v. 3M, 265 F.3d 1349 (Fed.*

Cir. 2001). In addition, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970).*

Applicants respectfully submit that Hennessy fails to describe all of the elements of independent claim 1 as amended, or any of the claims dependent thereon. Specifically, Hennessy fails to disclose the use of a single delivery device comprising two or more active agents selected from at least two types of anthelmintic compounds of differing chemical groups. Hennessy describes the preparation and administration of a single anthelmintic compound. For example, Hennessy makes no mention of combining different classes of anthelmintic. In fact, the uses the exclusive term "or" when describing the compound to be selected for the composition (Hennessy at column 3, line 28). Further, Hennesy teaches "the anti-parasitic agent is dispersed in a protein/lipid medium..." (Hennessy at column 4, lines 66-67, emphasis added). Taken in context, the use of the singular words "the" and "agent" implies the use of a single anthelmintic agent.

Regarding claim 2, the Examiner refers to Example 1 of Hennessy and concludes that Hennessy teaches the use of two or more anthelmintic compounds having different activities. Respectfully, that is not correct. Example 1 of Hennessy is divided into two parts: (A) and (B). Each part merely describes the preparation of an individual formulation. Part (A) describes the preparation of a formulation containing only albendazole (40 g) dispersed in 20 mL vegetable oil and emulsified with 14% casein solution. Part (B) describes the preparation of a formulation containing only ivermectin (100 mg) and 1 mL methylethyl ketone into vegetable oil, again emulsified with 14% casein. (Hennessy at column 6, lines 33-50). These two formulations are not described as combined, and are used independently of each other.

Further, the Examiner asserts that Hennessy teaches that benzimidazole and ivermectin are present together in the same composition because the two compounds are described in different quantities and with different target ratios in the overall composition. Office Action at page 5. However, the data in Example 1 show that Hennessy simply made a lot more of the albendazole formulation than the ivermectin formulation. There is no indication that a ration of 40 g albendazole and 100 mg ivermectin are the "relative proportions in order for appropriate ruminal intake" as stated by the Examiner. The two compounds are never disclosed as administered together by Hennessy. Furthermore, Hennessy does not disclose administration of

two or more anthelmintic formulations together. See also Example 2 where "Samples each containing approximately 5 mg of ABZ or 0.15 mg IVM were incubated ..." (Hennessy at column 6, lines 55-56, underlining added for emphasis). Figures 2 and 3 confirm the above interpretation, and show that less than 10% of the staged-release is either the ABZ or IVM preparation within 8 hours. This interpretation is made clear with examples 5, 6 7 and 9, in which the preparation contains only albendazole, and example 8 in which the preparation contains only ivermectin.

Finally, although Hennessy discusses target ratios, the ratio is merely the relative proportions of a single anti-parasitic agent that Hennessy indicates should be present respectively in the rumen, the abomasums and the small intestine of the treated animal. For example, the ratio of 1:4:5 (column 5, line 39) relates to the proportion of benzimidazole that should be presented in the rumen (1), abomasum (4) and the small intestine (5) of an animal. The ratio of 1:0.1:20 (column 5, line 40) relates to the proportion of a macrocyclic lactone that should be present in the rumen (1), the abomasum (0.1) and the small intestine (20) of an animal.

Accordingly, because Hennessy does not teach simultaneous use of two or more anthelmintic compounds from different classes, Hennessy fails to disclose the use of "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups," as recited in claim 1 as amended. For at least this reason, Hennessy fails to disclose all of the elements recited in independent claim 1. Since each of dependent claims 2, 4-8, 10, 11, 14, 17 and 19 depends either directly or indirectly on claim 1, Applicants submit that those claims are also not anticipated by Hennessy.

In view of the foregoing amendment and remarks, Applicants respectfully request that the Examiner withdraw the rejection of claims 1, 2, 4-8, 10, 11, 14, 17 and 19 under 35 U.S.C. § 102(b).

Rejection of Claims 1, 2, 3, 20, 21 and 25 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1, 2, 3, 20, 21 and 25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennessy in view of Whitehead (U.S. 6,030,637, hereinafter "Whitehead"). Specifically, the Examiner rejects claims 3, 20, 21 and 25, alleging that although Hennessy does not teach continuous release of active agents, such continuous release is taught by

Whitehead. The Examiner then concludes that it would have been obvious to one of ordinary skill in the art to utilize the bolus of Hennessy in combination with the continuous release allegedly taught by Whitehead. Applicants disagree.

The law dictates that in order to establish a *prima facie* case of obviousness, among other things, the prior art must teach or suggest all the claim limitations. (M.P.E.P. § 2143).

Applicant maintains that Claims 1, 2, 3, 20, 21 and 25 are not obvious over Hennessy in view of Whitehead because these references, either alone or combined, fail to teach or suggest all the limitations of any of these claims. As discussed above in the response to the rejection under 35 U.S.C. § 102(b), Hennessy fails to teach the element of "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." Applicant respectfully submits that Whitehead fails to remedy this defect. At best, Whitehead teaches a "bolus for delivery of pulsed doses of biologically active material." See Abstract. However, Whitehead fails to teach "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." as recited in claim 1 as amended. Because Whitehead fails to teach this missing feature, Whitehead fails to teach or suggest all of the claim limitations. Accordingly, for at least this reason, a *prima facie* case of obviousness has not been established.

Additionally, contrary to the assertions of the Examiner, Whitehead fails to teach continuous release of active anthelmintics. Specifically, Whitehead fails to teach release "at a substantially continuous rate," as recited in claims 3 and 25. Instead, Whitehead discloses a pulse release system. See Whitehead at column 1, lines 66-67 and column 2, lines 1-14 and 10-15. Whitehead specifically distinguishes the disclosed pulse release system from continuous release systems and states that pulse release systems "may be preferred to continuous release on the grounds that it can result in more economical use of an expensive active agent..." See Whitehead at column 1, lines 18-22 and 56-60. Accordingly, the disclosure of Whitehead teaches away from using continuous release systems. Additionally, there is no teaching in Whitehead as to how active agents would be released simultaneously (as opposed to sequentially) nor of any advantages which might be conferred by such simultaneous release. Thus, Whitehead fails to teach release "at a substantially continuous rate," as recited in claims 3 and 25. Because Whitehead fails to teach this missing feature, Whitehead fails to teach or suggest all of the claim

limitations. Accordingly, for at least this reason, a *prima facie* case of obviousness has not been established.

Applicants therefore submit that Claims 1, 2, 3, 20, 21 and 25 are not obvious under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Rejection of Claims 1 and 7-9 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1 and 7-9 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennessy. Specifically, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to use abamectin at a dose of 0.1 to 0.2 mg/kg/day because the optimization of a dosage range would be the result of routine experimentation. Applicants disagree.

The law dictates that in order to establish a *prima facie* case of obviousness, among other things, the prior art must teach or suggest all the claim limitations. (M.P.E.P. § 2143).

Applicant maintains that Claims 1 and 7-9 are not obvious over Hennessy. As discussed above in the response to the rejection under 35 U.S.C. § 102(b), Hennessy fails to teach the element of "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups," as recited in claim 1 as amended. Accordingly, for at least this reason, a *prima facie* case of obviousness has not been established.

Applicants therefore submit that Claims 1 and 7-9 are not obvious under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Rejection of Claims 1 and 10-12 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1 and 10-12 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennessy in view of IVS Annual Index of Veterinary Products (hereinafter "IVS"). Specifically, the Examiner asserts that although Hennessy does not teach the dosage of albendazole recited in claim 12, such dose range is taught by IVS. The Examiner then concludes that the dosage quantity disclosed by IVS would have rendered the claimed dose range obvious. Applicants disagree.

The law dictates that in order to establish a *prima facie* case of obviousness, among other things, the prior art must teach or suggest all the claim limitations. (M.P.E.P. § 2143).

Applicant maintains that Claims 1 and 10-12 are not obvious over Hennessy in view of IVS because neither of these references, either alone or combined, teach or suggest all the limitations of any of these claims. As discussed above in the response to the rejection under 35 U.S.C. § 102(b), Hennessy fails to teach the element of "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." Applicant respectfully submits that IVS fails to remedy this defect. At best, IVS teaches an effective dosage for a single anthelmintic agent. However, IVS fails to teach "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." as recited in claim 1 as amended. Because IVS fails to teach this missing feature, IVS fails to teach or suggest all of the claim limitations. Accordingly, for at least this reason, a *prima facie* case of obviousness has not been established.

Applicants therefore submit that Claims 1 and 10-12 are not obvious under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Rejection of Claims 1 and 13 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1 and 13 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennessy in view of Sanyal (Vet. Res. Comm. 20, 1996, 461-468, hereinafter "Sanyal"). Specifically, the Examiner asserts that although Hennessy does not teach the use of tricalbendazole, such use is taught by Sanyal as a low-level intraruminal anti-fluke agent. The

Examiner then concludes that it would have been obvious to one of ordinary skill in the art to use triclabendazole disclosed by Sanyal in the bolus of Hennessy. Applicants disagree.

The law dictates that in order to establish a prima facie case of obviousness, among other things, the prior art must teach or suggest all the claim limitations. (M.P.E.P. § 2143).

Applicant maintains that Claims 1 and 13 are not obvious over Hennessy in view of Sanyal because neither of these references, either alone or combined, teach or suggest all the limitations of any of these claims. As discussed above in the response to the rejection under 35 U.S.C. § 102(b), Hennessy fails to teach the element of "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." Applicant respectfully submits that Sanyal fails to remedy this defect. At best, Sanyal teaches use of triclabendazole as an anthelmintic agent. However, Sanyal fails to teach "a single delivery device comprising two or more anthelmintic compounds of differing chemical groups." as recited in claim 1 as amended. Because Sanyal fails to teach this missing feature, Sanyal fails to teach or suggest all of the claim limitations. Accordingly, for at least this reason, a *prima facie* case of obviousness has not been established.

Applicants therefore submit that Claims 1 and 13 are not obvious under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Rejection of Claims 1, 15, 16 and 18 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 1, 15, 16 and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennessy in view of Lewis (U.S. 5,733,566, hereinafter "Lewis"). Specifically, regarding claims 15 and 16, the Examiner asserts that although Hennessy does not teach the timed release of antiparasite active agents for the claimed time periods, such time periods are taught by Lewis. Regarding claim 18, the Examiner asserts that although Hennessy does not explicitly teach treatment of ecto-parasites, such activity is disclosed by Lewis. The Examiner then concludes that one of ordinary skill in the art would have expected reasonable success from limiting the temporal time period of release to the range disclosed by Lewis. Applicants disagree.

Applicant maintains that Claims 1, 15, 16 and 18 are not obvious over Hennessy in view of Lewis because it would not have been obvious to one of skill in the art to demonstrate release characteristics of a bolus based on the release characteristics and efficacy of material implanted under the skin. Lewis discloses anthelmintic-containing microparticles that are injected subcutaneously into animals and which are degraded under the skin. However, one of skill in the art would not have had a reasonable expectation of success because the release characteristics and efficacy of a micropartical material implanted under the skin would be quite different from that of an intra-ruminal bolus. Accordingly, the claimed time periods would not have been obvious.

Applicants therefore submit that Claims 1, 15, 16 and 18 are not obvious under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Double Patenting

The Examiner provisionally rejects claims 1 and 3 on the ground of nonstatutory double patenting over claims 1-4 and 20 of copending Application No. 11/908,708. Applicants will consider submitting a terminal disclaimer to overcome the rejection of Claims 1 and 3 once claims 1 and 3 of the instant application are found to be otherwise allowable.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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